ACRP
FOR LEARNING FOR LISTENING FOR LIFE

The Four Phases of Clinical Trials

	Phase 1	Phase 2	Phase 3	Phase 4
Primary Data Focus	Evaluation of pharmacology and toxicity of an investigation drug in humans **Pharmacokinetics:** Absorption, distribution, metabolism and excretion of the drug in the human body **Pharmacodynamics:** Effect of the drug on the human body **Safety & Tolerability:** Safe dose range of the drug for future trials	Evaluation of the safety and efficacy of an investigational drug **Focus on:** • Further assessment of the safety of the drug • Assessment of the effectiveness of the drug • Determination of dose and dosage regimen of the drug to be used in later studies • Evaluation of different target populations and therapeutic regimens of the drug • Investigation of drug-drug interactions	Confirmation of therapeutic efficacy **Focus on:** • Confirmation of therapeutic benefit • Monitoring of side effects • Dose-response relationship • Wider target population • Use at other stages of the disease • Interaction with other drugs or food • Development of instructions for use or product label	Post-approval trials that further investigate the therapeutic use of an investigational drug **Focus on:** • Optimization of the drug • Monitoring of long-term adverse events • Contraindicative drugs or diseases • Drug effectiveness and drug safety in populations not studied in earlier phases of research • Further investigation of drug-drug interactions, dose-response and safety profile, epidemiology, morbidity or mortality
Subjects	Healthy volunteers (sometimes seriously ill patients with no other options or when drug is toxic to healthy volunteers, such as cytotoxic chemotherapy agents)	Subjects with the condition under study	Subjects with the condition under study	Patients with the condition under study
Sample Size	6-20 subjects, typically including healthy subjects	50-200 subjects having a target disease	200-1,000 subjects	Hundreds of subjects, and subjects may be users of the drug or individuals belonging to new populations that need further investigation, such as children, the elderly, other diseases, etc.
Design	Dose escalation, typically open-label, single center	Blinded, randomized, controlled, strict inclusion / exclusion criteria	Blinded, randomized, controlled, general population	Usually blinded, randomized, controlled
Duration	Short, ranging from 9-18 months	One to three years	Two to five years	One to three years or longer, if required by the regulatory authority